CASEREVIEW

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Notice of Independent Review Decision

December 2, 2015

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**
Intrathecal pump refill x3 with CPT codes 62369 x 3 (Anal sp inf pmp w/reprg & fill), 62370 x 3 (Anl sp inf pmp w/mdreprg & fill), J0475 x 3 (injection, baclofen, 10 mg), J0310 x 3 (Unknown), J2270 x 3 (Injection, morphine sulfate, up to 10 mg)

**A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:**
This physician is a Board Certified Anesthesiologist with over 8 years of experience, including Pain Management.

**REVIEW OUTCOME:**

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

**PATIENT CLINICAL HISTORY [SUMMARY]:**
The claimant is a male who was injured on XX/XX/XX. He underwent a laminectomy/fusion at L4-S1 in 2000 with continued severe back pain and leg pain. It was noted a facet block protocol was denied. The patient had intrathecal catheter which was palliative. Associated symptoms included numbness in the bilateral thighs and feet and weakness of the involved with progressive episodes of falling. It was noted that he fell at least once a week.

On November 3, 2014, the claimant presented for a pump refill. Driver medication: Fentanyl 5.5 mg/ml. Concurrent medications; Baclofen 0.91 mg/ml and Morphine 1.83 mg/ml. Infusion type; FLEX. Change in concentration: none. Change in rate: none. Total daily dose of driver: 3.15 mg/d.

On March 11, 2015, the claimant presented for a pump refill. Driver medication: Fentanyl 5.5 mg/ml. Concurrent medications; Baclofen 0.91 mg/ml and Morphine 1.83 mg/ml. Infusion type; FLEX. Change in concentration: none. Change in rate: none. Total daily dose of driver: 3.15 mg/d.

On May 4, 2015, the claimant presented with complaints of constant back pain with burning and stated that his back locks up. Pain score was 9/10. noted that the claimant had an increase of pain in his lower back. He had

been attempting to lower the Fentanyl and increase the Morphine, but would leave the Fentanyl alone and increase the Morphine in his pump to 3 mg/ml. The claimant had reported doubling up on his oral Morphine which had improved his pain. Pump telemetry was performed and the pump was reprogrammed with 5% increase to daily rate for better symptom control until his next pump refill. Current Medication: Baclofen 20 mg tablet, Neurontin 300 mg capsule, Soma 350 mg tablet, Trazodone 50 mg tablet, Zolpidem Tartrate 10 mg tablet, Morphine Sulfate Er 30 mg cap.

On May 11, 2015, the claimant presented for a pump refill. Driver medication: Fentanyl 5.5 mg/ml. Concurrent medications; Baclofen 0.91 mg/ml and Morphine 3 mg/ml. Infusion type; FLEX. Change in concentration: Change in ration of medications; BACLOFEN AND MORPHINE CONC/RATE INCREASED THIS REFILL FOR BETTER SYMPTOM CONTROL. Change in rate: none. Total daily dose of driver: 3.62 mg/d.

On July 8, 2015, the claimant presented for a pump refill. Driver medication: Fentanyl 5.5 mg/ml. Concurrent medications; Baclofen 1 mg/ml and Morphine 3.5 mg/ml. Infusion type; FLEX. Change in concentration: none. Change in rate: none. Total daily dose of driver: 3.62 mg/d.

On August 3, 2015, the claimant presented for low back pain that is worse with sitting than standing. He reported not being able to sit for long periods of time. The claimant also reported that he has to go through certain movements before he can get out of bed. Current Medications: Morphine Sulfate Er 30 mg cap; Baclofen 20 mg tablet; Neurontin 300 mg capsule; Trazodone 50 mg tablet; Zolpidem Tartrate 10 mg tablet. Upon completion of the standing provocation, the patient was leaning forward which really caused an increased in pain. made some blind changes to the noon and 6 pm bolus. He changed 12 bolus from 230 to 200 and increased the 6 pm bolus. He increased the daily dose to 3.8 micrograms per day. He increased the 6 am dose from 230 to 260.

On September 2, 2015, the claimant presented for a pump refill. Driver medication: Fentanyl 5.5 mg/ml. Concurrent medications; Baclofen 1 mg/ml and Morphine 3.5 mg/ml. Infusion type; FLEX. Change in concentration: none. Change in rate: none. Total daily dose of driver: 3.8 mg/d.

On September 21, 2015, the claimant presented for a pump evaluation and possible change. Since the last encounter he complained of having increased “shooting pain down both legs”. Driver medication: Fentanyl 5.5 mg/ml. Total daily dosage of driver/day. Fentanyl 5.5 mg/ml 4.0 mg/day (5% increase to daily rate). Change in rate: Increased rate.

On October 8, 2015, UR. Rationale for Denial: The Official Disability Guidelines Pain Chapter provides guidance including criteria for use of implantable pain pump reservoir systems, including the request to refill such a device with intrathecal delivery of pain medications. There are a number of specific requirements that must be met, which are outlined clearly by these guidelines. In this case, the patient has been undergoing refills approximately every two months with morphine, baclofen, and Fentanyl. The guidelines do recommend fills with morphine as a first stage and baclofen may also be added at a later stage to help control muscle spasms. However, the guidelines also clearly state that the use of Fentanyl in an intrathecal delivery system is not FDA approved and has little clinical data to support its use. Additionally, while the provider has requested a series of 3 refills for this patient’s pain pump to be performed every other month, the guidelines also note that each refill presents an opportunity for reevaluation and review of the patient’s response to the intrathecal pain medication delivery system and monitoring for side effects and appropriate dosing. Specifically with this patient, each of the last few visits have apparently resulted in adjustments to the delivery rate and distribution of the medication throughout the day for better pain control with the patient. The guidelines support evaluation of the patient’s response and tolerance of the drug delivery system as mentioned at refills and accordingly, a set of 3 refills without re-review of appropriate clinical information is not recommended. Additionally, because the requested refill includes CPT code J0310, which is injection of an unknown substance that is most likely the Fentanyl that has been given to the patient, this portion of the refill is specifically not supported by the appropriate guidelines. Accordingly, for these reasons, at this time, I am unable to establish medical necessity criteria for the requested intrathecal pump refills times 3 as stated.

On October 22, 2015, UR. Rationale for Denial: The physician is attempting to adjust the medications for better pain control. Pump reservoir size, drug concentration, dose, and flow rate will dictate the time between refills and will vary based on this information. The documentation does not substantiate this request at this time. The patient has been receiving refills approximately every two months with morphine, Baclofen, and Fentanyl. Morphine is recommended as a first state and baclofen may be added at a later stage to help control muscle spasms. However, Fentanyl for use with an intrathecal delivery system is not FDA approved and has little evidence-based data to support its use. The Morphine and Baclofen would be supported; however, the Fentanyl as well as the unknown substance is not supported. Therefore, medical necessity is not established for this request.

On October 29, 2015, the claimant presented for refill of medications. He reported the increase on his pump had helped and he was sleeping better at night. Pain most of the time was rated an 8, at least intensity a 7 and at worst a 10. Prescribed Morphine Sulfate Er 30 mg cap and Neurontin 300 mg capsule was changed to 600 mg 1 po q8h. On evaluation he was positive for back and right knee pain. He was positive for numbness, tingling and bilateral lower extremity weakness. Assessment: Chronic postprocedural pain; low back pain; unspecified injury to unspecified level of lumbar spinal cord, sequel; intrathecal catheter with programmable pump. Medications were refilled for the pump with no changes.

**ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:**

The previous adverse determinations are partially overturned. Pump reservoir size, drug concentration, dose, and flow rate are all factors that will dictate the time between refills and will vary based on this information. The patient has been receiving refills approximately every two months with morphine, Baclofen, and Fentanyl. Morphine is recommended as the first line medication and baclofen may be added at a later stage to help control muscle spasms. However, there is little evidence to support the use of fentanyl with an intrathecal delivery system and is not FDA approved. The morphine and Baclofen would be supported; however, the Fentanyl as well as the unknown substance is not supported. Therefore, medical necessity is established for the Intrathecal pump refill x3 with CPT codes 62369 x 3 (Anal sp inf pmp w/reprg & fill), 62370 x 3 (Anl sp inf pmp w/mdreprg & fill), J0475 x 3 (injection, baclofen, 10 mg), J2270 x 3 (Injection, morphine sulfate, up to 10 mg). Medical necessity is not established the Fentanyl, J0310 x 3 (Unknown).

PER ODG:

**Medications for IDDS if determined to be medically necessary:**
*First stage:* Morphine is generally the initial IDDS medication. The maximum recommended dose for this drug is 15 mg/day with a concentration of 20 mg/mL. An alternative non-FDA approved medication is hydromorphone. The maximum recommended dose for this medication is 4 mg/day with a concentration of 10 mg/mL. Other opioids (including Fentanyl and Sufentanil) have been used for intrathecal chronic non-malignant pain but are non-FDA approved and have little research associated with their use. (Waara-Wolleat, 2006) (Deer, 2007) The previous 2003 Polyanalgesic conference recommended a maximum dose of intrathecal morphine at 15 mg/day with a maximum concentration of 30 mg/mL. They also recommended a maximum dose of hydromorphone of 10 mg/day with a concentration of 30 mg/mL. (Hassenbusch, 2004) The newer maximum concentrations were recommended, in part, to prevent granulomas.
*Second stage:* If side effects occur, an upper limit of dosing is reached, or neuropathic pain is present, clonidine is next recommended as an addition to an opioid (maximum recommended dose of 1 mg/day and a concentration of 2 mg/mL). Bupivacaine has also been recommended as an alternative to clonidine (maximum dose of 30 mg/day and a concentration of 40 mg/mL). Clonidine, which is FDA approved for intrathecal delivery, is thought to provide analgesic effect via a non-opioid mechanism. It has been found to offer only short-term relief when used as a single agent. (Deer, 2007)
*Third stage:* The recommendation has been made to add both clonidine and bupivacaine. Baclofen has been used to treat intractable spasticity from brain injury, cerebral palsy, and spinal cord injury and has resulted in improvement in muscle tone and pain relief. (Guillaume, 2005) See also Ziconotide (Prialt®), which is recommended after documentation of a failure of a trial of intrathecal morphine or hydromorphone (Dilaudid).

*Refills:* IDDSs dispense drugs according to instructions programmed by the clinician to deliver a specific amount of drug per day or to deliver varying regimens based on flexible programming options, and the pump may need to be refilled at regular intervals. The time between refills will vary based on pump reservoir size, drug concentration, dose, and flow rate. A programming session, which may occur along with or independent of a refill session, allows the clinician to adjust the patient's prescription as well as record or recall important information about the prescription. (Hassenbusch, 2004) According to the FDA, the manufacturer's manuals should be consulted for specific instructions and precautions for initial filling, refilling and programming. (FDA, 2010) For most pumps, the maximum dose that can be delivered between refills is 1000mg. If refills are usually administered after 16 to 17 mL have been infused, and most pumps are 18-20mL, the minimum time between each visit is 42 days if the daily dose rate is 20 mg/day. Given that a refill visit presents a good opportunity for monitoring, this panel suggested that the concentration be adjusted to allow refill visits a minimum of every 4 to 6 weeks, and maximum of every 2–3 months. (Bennett, 2000)

**A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:**

- ☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- ☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- ☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- ☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- ☐ **INTERQUAL CRITERIA**
- ☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- ☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- ☐ **MILLIMAN CARE GUIDELINES**
- ☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- ☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- ☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- ☐ **TEXAS TACADA GUIDELINES**
- ☐ **TMF SCREENING CRITERIA MANUAL**
- ☐ **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- ☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**